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Alessandro Luigi Spadini

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EXAMINER

RAE, CHARLESWORTH E

ART UNIT

PAPER NUMBER

1614

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/730,218

Applicant(s)

SPADINI ET AL.

Examiner

Charlesworth Rae

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6, and 9-39 is/are pending in the application.
- 4a) Of the above claim(s) 18-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 7/29/05; 6/23/05; 12/8/03.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicant's response with traverse to the Restriction/Election requirements, mailed 3/29/07, electing invention I, and the organophilic particle as the stabilizer species, is acknowledged and made of record. Applicant's statement regarding the following: claims 17-33 are withdrawn, claims 7-8 cancelled, and claims 1 and 6 amended, is acknowledged and made of record.

The information disclosure statement filed July 28, 2005 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. It is noted that the citing of the International Search Report (ISR) on the above-referenced information disclosure statement is improper as the ISR is not considered to be a publication.

The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

### **Restriction/Election of species**

Applicant's traversal argument that "the amount of specific ingredient" requirement is beyond the scope of a proper election of species requirement is found persuasive. This election requirement is therefore withdrawn. The restriction/election requirements are made final.

### **Status of the Claims**

Claims 1-39 are currently pending in this application and are the subject matter of the Office action.

Claims 7-8 have been cancelled; and claims 1 and 6 have been amended.

Claims 18-39 are withdrawn for purposes of examination on the merits for being directed to non-elected subject matter. It is noted that claim 17 is being treated as being drawn to the elected species. Applicant's above referenced statement regarding the pending/withdrawn is being disregarded. However, applicant is invited to clarify this issue.

Claims 1-6, and 9-17 are presented for examination.

### **Objections**

The disclosure is objected to because of the following informalities: the word ".A" appears in claim 1. The period before the "A" is objected to. Applicant is requested to correct this apparent typographical error.

Also, claim 1 is objected to for having an improper period as follows: "a.", "b.", "c.", "d.", and "e." This objection may be overcome by deleting the period following the letters "a," "b," "c," "d," and "e."

**Claim Rejection – 35 USC 112 – First Paragraph - Enablement**

Claims 1-6 and 9-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the exemplified compositions comprising a dispersed phase including a first component being capable of chemically reacting with a second component that is different from the first component, does not reasonably provide enablement for any and all compositions comprising a dispersed phase including any first component, the first component being capable of chemically reacting with any second component that is different from the first, a continuous phase composed of any substantially anhydrous carrier, at least one of any organophilic particle stabilizer in the dispersed phase, wherein the first component is substantially unsolvated in any substantially anhydrous carrier, and any anionic surfactant in a concentration of at least 2% by wt. when the at least one stabilizer consists solely of waxy particles, amphipathic compounds or polymers, or a combination thereof. This is a scope enablement rejection.

To be enabling, the specification of the patent application must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1561 (Fd. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated that:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if its is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed to enable the

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determination of how to practice a desired embodiment of the claimed invention. PPG v Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth in *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 wherein, citing *Ex parte Forman* 230 USPQ 546 (BdApls 1986) at 547 the court cited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. *In re Fisher*, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill of those in the art.

The invention in general relates to a skin care or cleansing composition comprising: a) a dispersed phase including an active ingredient (or first component)

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capable of chemically reacting with a different active ingredient (or second component) that is different from the first second component; b) a continuous phase composed of substantially anhydrous carrier; c) at least one stabilizer contained in the dispersed phase; d) wherein the first component is substantially unsolvated in the carrier; and e) an anionic surfactant in a concentration of at least 2% by wt. When the at least one stabilizer consists solely of waxy particles, amphipathic compounds or polymers, or combination thereof.

The relative skill of those in the art is high, generally that of an M.D. or Ph.D. It is noted that the chemical/pharmaceutical arts is generally unpredictable, requiring each embodiment to be individually assessed for physiological activity. The more unpredictable an area, the more specific enablement is necessary in order to satisfy the statute. (see *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970)).

Oblong et al. (US Patent 5,939,082) teach compositions comprising a) a vitamin B3 compound, b) a second active, and c) a carrier (columns 2- 30). Oblong et al. teach that the compositions comprise a dermatologically acceptable carrier within which the vitamin B3 is incorporated to enable the vitamin B3 compound and optional actives to be delivered to the skin at an appropriate concentration; the carrier can act as a diluent, dispersant, solvent, or the like for the active(s) which ensures that it can be applied and distributed evenly over the selected target at an appropriate concentration (column 6, lines 57-62). The carrier may contain one or more dermatologically acceptable solid, semi-solid or liquid fillers, diluents, solvents, extenders and the like; the carrier may be solid, semi-solid or liquid (column 6, line 66 to column 7, line 58). Oblong teaches that

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preferred carriers comprise an emulsion such as an oil-in-water emulsions, water-in-oil emulsions, and water-in-silicone emulsions (column 7, lines 59-61). Oblong et al. disclose that it would be understood by a skilled artisan that a given component will distribute primarily into either the water or oil/silicone phase, depending on the water solubility/dispersibility of the component in the composition; preferred vitamin B3 compounds distribute primarily into the aqueous phase (column 7, lines 61-66). Oblong et al. teach emulsions which contain a lipid or oil, and which also contain a humectant, such as glycerin, and an emulsifier (of about 1 to 10% of the weight of the carrier); the emulsion may also contain an anti-foaming agent (col. 8, lines 1-25). Oblong et al. teach a continuous silicone phase containing a polyorganosiloxane oil (col. 8, line 31 to col. 10, line 36); and a dispersed aqueous phase containing water, or a combination of water and one or more water soluble or dispersible ingredients, including thickeners, acids, bases, salts, chelants, gums, water soluble or dispersible alcohols and polyols, buffers, preservatives, sunscreens, coloring agents, and the like (col. 10, lines 36-55). Oblong et al. disclose various dimethicone copolyols and other silicone surfactants useful as emulsifiers, including polydimethylsiloxane polyether copolymers with pendant polyethylene oxide sidechains (col. 11, line 66 to col. 12, line 56). Oblong et al. disclose that various non-ionic and anionic emulsifying agents such as sugar esters and polyesters, alkoxyated sugar esters and polyesters, fatty acid amides, acyl lactylates, soaps, and mixtures of non-ionic/anionic emulsifying agents (col. 12, lines 57-66). Oblong et al. teach that a wide variety of anionic surfactants are useful for use in the composition, including: alkoyl isethionates, and the alkyl and alkyl ether sulfates, soaps



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(i.e. alkali metal salts, e.g. sodium or potassium salts) of fatty acids (e.g. wherein the fatty acids are derived from natural sources such as palm oil, coconut oil, soybean oil, castor oil; or synthetically prepared) (col. 16, lines 7-48). Oblong et al. further teach that the composition may comprise a wide variety of optional components provided that such optional components are ***physically and chemically compatible with the essential components of the composition and do not unduly impair stability, efficacy of the composition*** (col. 19, line 17 to col. 30, line 9). Oblong et al. teach that the composition is preferably formulated to have a pH of 10.5 or below (col. 19, lines 11-16).

Leyland et al. (GB 2,242,358 A; **already made of record by applicant**), teach cosmetic formulations comprising a cosmetically acceptable carrier immiscibly combined with a water-in-oil emulsion comprising an aqueous phase dispersed within an oil phase by means of an emulsifying agent wherein a component capable of interaction with an ingredient of the carrier is incorporated within the aqueous phase of the emulsion (abstract). Lelyland et al. teach that difficulties may be encountered in combining certain ingredients into a single formulation because some substances useful in cosmetic formulations may interact with other substances (page 1, second para.; and page 3). Leyland et al. disclose specific procedures for preparing the disclosed compositions therein (see Examples 1-18; pages 16-35).

## 2. The breadth of the claims

The instant claims are relatively broad. For example, claim 1 encompasses any active ingredient as the first component, and all other active ingredients/second components that are different from the first component. Further, the

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claim limitation "*the first component being capable of chemically reacting with a second component that is different from the first,*" is reasonably construed to mean that the second component may be in the dispersed phase, or continuous phase, or both.

Alternatively, the chemical reaction between component 1 and 2 may reasonably not occur in the composition, if for instance, the second component is not a specific

component of the composition. Applicant discloses that "chemically reacting

as used herein is defined as but is not limited to gas

formation, redox reactions, lysis (e.g. hydrolysis and

perhydrolysis), bond cleavage and the like; and does not include

reactions or interactions that manifest themselves solely by one

or more of the following: 1) color formation or color change, 2)

self-polymerization and 3) exothermic or endothermic solvation

processes; chemical reactions are not excluded from the

invention merely because they are accompanied by color change,

self-polymerization, and exothermic or endothermic salvation

processes if they also include at least one other definable

chemical reaction (para. 0012)." Preferably the first and second

components are not encapsulated in a barrier material prior to

reaction or at any time (para. 0012). However, in the absence disclosure

of the specific reactants (e.g. the first component, and the second component), and the

specific conditions favorable for effectuating the chemical reaction between the first

component and second component, someone of skill in the art would not be able to

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reasonably predict where the chemical reaction between the first and second would occur (e.g. in the dispersed aqueous phase vs. continuous phase oily phase), or the pH or temperature or viscosity that could favor a chemical reaction between the first component and second component to practice the instantly claimed invention. The term "*capable*" as defined by the Webster's New Collegiate Dictionary (1981, page 162) means **"having attributes required for performance or accomplishment;"** which is not the same as actually performing a given function i.e. actually causing a chemical reaction between the first component and the second component.

Applicant discloses that the term "**substantially anhydrous**" as used herein means that the carrier is sufficiently free of water to prevent substantial solvation or reaction with the first component; **substantially anhydrous** as used herein can also mean that the carrier contains water but that the water is isolated or otherwise prevented from solvating or reacting with the first component (para. 0013).

Applicant asserts that surprisingly it has been found that a skin care or cleansing composition can be formulated which has a substantially solvated or continuous and a **substantially unsolvated** or discontinuous phase where at least two components of the discontinuous phase may either react with each other when blended with water or where at least one component may itself react with the water so as to provide a unique cleansing, skin benefit, sensory signal or a combination thereof to the user. Such a composition also solves the problem of providing a concentrated cleansing

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or skin benefit component in a convenient liquid or solid form for consumer use (para. 0005). Also, claim 1, recites the terms "*substantially anhydrous carrier*," and the term "*the first component is substantially unsolvated in the carrier*," which are very broad terms as the specific term "substantially" is defined to mean "considerable in quantity" (Webster's New Collegiate Dictionary, 1981, page 1153). While claim 2 recites the term "*the second component is substantially unsolvated in the carrier*," which is also very broad. In addition, claim 1 recites the terms "*at least one stabilizer contained in the dispersed phase*," which could reasonably be construed to mean one or a million or more stabilizers as the term has no upper limit; and the term "*an anionic surfactant in a concentration of at least 2% by wt.*," which given their broadest reasonable interpretation could reasonably encompass an anionic surfactant in a concentration of 100% of the composition as the claimed concentration range does not have an upper limit. Because the amount of anionic surfactant, number of stabilizers, the specific first component, and specific second component, for example, could reasonably vary widely, the level of predictably in practicing the claimed invention would be greatly diminished.

3. The amount of direction or guidance provided and the presence or absence of working examples

Applicant discloses a number of examples of compositions comprising a Hydrophilic continuous phase and a combination of anionic and amphoteric surfactants (see Example 1, page 28), and other examples, wherein the ingredients of the composition are provided in the form of a list (Examples 1-11; pages 28-40). No specific guidance is provided to for actually making/preparing the instant claimed

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composition wherein the specific ingredients in the dispersed phase and the continuous phase are specifically delineated, unlike in the case of the prior art (Leyland et al., pages 16-35).

4. The quantity of experimentation necessary

In view of applicant's disclosure, it is reasonable to surmise that the level of uncertainty in the art would require one skilled in the art to conduct more than routine experimentation in order to practice the claimed invention. Thus, based on the known unpredictability of the art (as discussed *supra*) and in the absence of experimental evidence commensurate in scope with the claims, the skilled artisan would not accept the assertion that the instantly claimed invention could be predictably practiced as claimed.

For the reasons stated above, claims 1-6 and 9-16 are rejected under 35 USC 112, first paragraph, for lack of scope enablement because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with the claims.

**Claim rejections – 35 USC 103(a)**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For purposes of claim rejections under 103(a), the term "*a dispersed phase including a first component, the first component being capable of chemically reacting with a second component that is different from the first,*" as recited in claims 1, is reasonably construed to mean the "discontinuous or external" phase of an emulsion wherein any ingredient present in the dispersed phase is reasonably construed to be the "first component". The "*first component,*" as recited in claim 1, is reasonably construed to be capable of reacting with any other component "*second component,*" that is present in the composition or external to the composition i.e. the first component may reasonably react with a second component e.g. hair or skin, at the point of use of the composition; or may be capable of reacting with a carrier in the composition or different ingredient in the composition.

The term "*substantially anhydrous carrier,*" as recited in claim 1, is reasonably construed to mean any carrier that is not 100% water. The term "*carrier*" given its

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broadest reasonable interpretation is construed to include any solvent, or diluent, or vehicle that is not comprised of 100% water.

The term "*first component is substantially unsolvated in the carrier,*" as recited in claim 1, is reasonably construed to mean any first component that is completely present or contained in the dispersed phase, wherein the dispersed phase is dispersed within an oil phase by means of an emulsifying agent.

The term "*an organophilic particle,*" as recited in claim 1, is reasonably construed to mean any ingredient that is present in the dispersed phase in the form of a particle i.e. not completely dissolved/solubilized in the dispersed phase, including powders, semi-solids, and colloidal particles (Steadman's Medical Dictionary, 1995; page 1259).

Claims 1-6, 9-11, and 13-17 are rejected as being unpatentable over Beerse et al. (US Patent 6,294, 186).

Beerse et al. teach compositions comprising water-in-silicone emulsions having a **dispersed phase** (i.e. limitation "a" of instant claim 1) including a **first component** (salicyclic acid; limitation "a" of instant claim 1), and a **second component** (e.g. sodium chloride; limitation "a" of instant claim 1), glycerin and denatured ethanol (i.e. a water soluble **anhydrous fluid/carriers** = substantially anhydrous carrier limitation of item "b" of instant claim 1, and claim 9), and PVP is reasonable construed to be an **organophilic particle/surfactant/stabilizer** (satisfies the "organophilic particle" limitation of claim 1; and the stabilizer limitation of claim 1; and the surfactant limitation "d" of claim 1 (col. 51, Example 16-18). It is noted that the limitation "*an anionic*

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*surfactant in a concentration of at least 2% by wt. when the at least one stabilizer consists solely of waxy particles, amphipathic compounds, or a combination thereof,"* recited as item "e" of instant claim 1, is reasonably construed to be essential only *when the at least one stabilizer consists solely of waxy particles, amphipathic compounds, or a combination thereof*" (col. 51, Example 16-18). The first and second components taught by Beerse et al. are reasonably construed to be capable of chemically reacting via non-polymerization (limitation recited in instant claim 3). The first component is construed to be "*substantially unsolvated in the anhydrous carrier*" in the presence of the PVP ( limitation "d" of instant claim 1, and limitation recited in instant claim 2) (col. 51, Example 16-18). However, Example 21-25 teach a liquid handsoap containing anionic surfactants which are reasonably construed to be substantially unsolvated by the anhydrous carrier (e.g. ammonium lauryl sulfate and ammonium laureth-3 sulfate are taught by Beerse; limitation recited in instant claim 11; see col. 53). Beerse et al. teach compositions comprising a **continuous phase** (limitation "b" of instant claim 1; see col. 51, Example 16-18), and **emulsifying agents** (e.g. aluminum starch octenyl succinate; synthetic wax; col. 51, Example 51). Beerse et al. teach composition containing additional ingredients, including pemulen and carbomer (= hydrophilic structuring polymer; see col. 51, Example 14-15); hydrogen peroxide (col. 56, Example 33-35); and petrolatum, propylene glycol, cetareth-10, cetearyl alcohol, and PEG-330 (see cols. 56-57, Example 33-35). Beerse et al. also teach powders inorganic powders (e.g. gums, chalk, Fuller's earth, kaolin, iron oxide, mica, sercite, muscovite, phlogopie, synthetic mica, lepidolite, biotite, Lithia mica, vermiculite, magnesium carbonate,



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calcium carbonate, aluminum silicate, starch, smectite clays, alkyl and/or trialkyl aryl ammonium smectites, chemically modified magnesium aluminum silicate, organically modified montmorillonite clay, hydrated aluminum silicate, fumed silica, aluminum starch octenyl succinate barium silicate, calcium silicate, magnesium silicate, strontium silicate etc.), which are reasonably construed to be organophilic particles as these particles are reasonably construed to attract each other through nonpolar mechanisms (limitation recited in instant claims 6 and 16; see col. 41, lines 1-50; see Steadman's Medical Dictionary (27<sup>th</sup> edition. <http://www.thomsonhc.com/pdrel/librarian/PFActionId/pdrcommon.stedmans.StedmansDocumentAction/DocumentDefinition/pdrcommon.Stedmans/DocumentId/28628/PFPUI/Xm1qVKg1WARh1Q/CS/186AC6>); instant claim 6 also recites organophilic silica, organophilic clay. Beerse et al. teach that the **particle size** of the powders are about 0.01 to about 100 microns, which overlaps with the range of particle size recited in instant claims 4-5. The limitation "wherein the first and second components do not substantially react with each other until dispersed or dissolved in water," as recited in claim 10, is reasonably construed to be within the skill and knowledge of an artisan skilled in the art. Beerse et al. teach structuring agents (limitation recited in claim 12; see col. 17, lines 33-64). The formation of lamellar, hexagonal, or cubic surfactant phases upon contact with water at 25 ° C, as recited in instant claim 12, is construed to be within the knowledge and skill of an artisan skilled in the art (col. 13, line 10 to col. 14, line 40; and col. 17, lines 33-64). Beerse et al. teach that emulsifiers having an HLB value outside of from about 2 to about 14 can be used in combination (col. 15, lines 7-35). Beerse et al. teach compositions comprising a carrier

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(i.e. the emulsion) wherein the carrier contains an oil (i.e. silicone oil = cyclomethicone), an emulsifier (e.g. cetyl palmitate, or triberhenin), and wherein the stabilizer is an organophilic clay (= hectorite); and the composition contains a total of at least about 10% of reactive dispersed solids by wt., which reasonably overlaps with the limitation of at least about 10% of reactive dispersed solids by wt. recited in instant claim 16, as the term "*at least about 10%*" as recited in instant claim 16, is reasonably construed to encompass amounts above 1%. (see Example 11-13, col. 50 ). Beerse et al. teach a continuous phase containing a polyorganosiloxane oil (between about 50% and 99.9% by weight of organosiloxane oil and less than about 50% by weight of a non-silicone oil, which reasonably meet the instant claimed limitation of "*a substantially anhydrous carrier*" as recited, for example, in instant claim 1 (column 12, lines 59-63). Beerse et al. teach that polyalkylsiloxanes useful in the composition include polyalkylsiloxanes with viscosities of from about 0.5 to about 1,000, 000 centisokes at 25 ° C; suitable non-silicone oils for the continuous silicone phase, include e.g. mineral oil, vegetable oils, synthetic oils, and semi-synthetic oils (col. 13, line 10 to col. 14, line 40). Beerse et al. teach a dispersed phase of the composition wherein the aqueous dispersed phase is a dispersion of small aqueous particles or droplets suspended in and surrounded by the continuous silicone phase; the aqueous phase can be water and one or more soluble or dispersible ingredients, including e.g. thickeners, acids, bases, salts, chelants, gums, water-soluble or dispersible alcohols and polyols, buffers, preservatives, sunscreens agents, and colorings (col. 14, lines 41-59). Instant claims 13-15 and 17 recite limitations (e.g. *first component is capable of producing a gas in*

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*aqueous solution when reacted with an acid and the second component is an acid or forms an acid in the presence of water; the first component is capable of generating a peroxide compound when dissolved in water; the first component is capable of generating sulfide ions when reacted with an alkaline material in water; the first component is a solid or semi-solid containing dissolved carbon dioxide*), which are reasonably construed to be within the skill and knowledge of an artisan skilled in the art. For example, Beerse et al. exemplify a composition comprising hydrogen peroxide (limitation recited in claim 14; see Example 33-35, col. 56).

Based on the examples taught by Beerse et al., someone of skill in the art at the time the instant claimed invention was created would have been motivated to create the instant inventive concept, for example, to impart immediate as well as residual effects from a topical composition comprising a first component anti-viral agent and a second component antibacterial agent (col. 1, lines 44-50). Thus, someone of skill in the art at the time the instant invention was made would have deemed it obvious to created the instant claimed invention with a reasonable expectation of success.

The following references are added to show the general state of the prior art: Remington's (Remington's Pharmaceutical Sciences. 16<sup>th</sup> ed. (1980); Ha et al. (US Patent 5,997,887; SaNogueira, Jr. et al. (US Patent 6,174,533), Unger et al. (US Patent 6,403,065); Robinson et al. (US Patent 6,492,326); Naser et al. (US Patent 6,290,943; **already made of record by applicant**), Oblong et al. (US Patent 5,939,082); and Patel et al. (US Patent 6,248,363)

**Relevant Art of Record**

Leyland et al. (GB 2,242,358 A) made of record and relied upon is considered pertinent to applicant's invention. It is noted that Leyland et al. (GB 2,242,358 A), which is cited in the instant PTO-1449, filed 6/23/05, disclose cosmetic formulations comprising a cosmetically acceptable carrier immiscibly combined with a water-in-oil emulsion comprising an aqueous phase dispersed within an oil phase by means of an emulsifying agent.

Claims 1-6, and 9-17 are also rejected under 103(a) as being unpatentable over Leyland (GB 2,242, 358), in view of Diec et al. (US Patent 6,607,733).

Leyland et al. teach cosmetic formulations comprising a cosmetically acceptable carrier immiscibly combined with a water-in-oil emulsion comprising an aqueous phase dispersed (limitation "a" of claim 1) within an oil phase (limitation "b" of claim 1) by means of an emulsifying agent (limitation "c" of claim 1), wherein a component (satisfies the first component limitation of claim 1) capable of interaction with an ingredient of the carrier (satisfies the second component limitation of claim 1) is incorporated within the aqueous phase of the emulsion (abstract; see page 1, line 5 to page 15, line 22; see also reference claims). Reference Example 15 teach a composition comprising sodium lauryl ether sulphate (limitation "e" of instant claim 1); which is a compound capable of reasonably generating sulfide ions when reacted with an alkaline material and water (limitation recited in claim 15); chlorhexidene gluconate, which is a compound reasonably capable of generating a peroxide compound (limitation recited in claim 14); formaldehyde, which is a compound reasonably capable

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of producing a gas in aqueous solution when reacted with an acid .e.g. citric acid (limitation recited in claim 13) and the second component is an acid or forms an acid in the presence of water (see reference claim 39). Leyland et al. teach that the emulsion may contain a single emulsifying agent or a mixture of emulsifiers (limitation "c" of claim 1; see also page 4, line 22 to page 6, line 10). Leyland et al. do not specifically teach lamellar, hexagonal, or cubic forms of surfactant phases, however.

Diec et al. (US Patent 6,607,733) teach water-in-oil (W/O) emulsions comprising substituted polysaccharide thickeners, for example, cetylhydroxyethylcellulose, can be advantageously used for physiological activity in the context of cosmetic or pharmaceutical action because of its hydrophobicity (col. 14, lines 22-33). Diec et al. teach compositions comprising 0.001-20% by weight of one or more thickeners in an O/W emulsion can pass through phase inversion by altering the temperature to produce W/O emulsions containing lamellar phases, bicontinuous phases or cubic, hexagonal or inversely hexagonal phases (limitation recited in claim 12; col. 14, lines 25 -54). The term thickeners is construed to mean a structuring agent, as recited in instant claim 12.

Based on the teaching of the advantageous hydrophobicity produced by the structuring agents taught by Diec et al., someone of skill in the art would have been motivated to combine the teaching of Leyland et al., in view of Diec et al., al. to create a waterproof composition.

Thus, someone of skill in the art at the time the instant invention was made would have deemed it obvious to create the instant claimed invention with a reasonable expectation of success in view of Leyland et al., in view of Diec et al.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

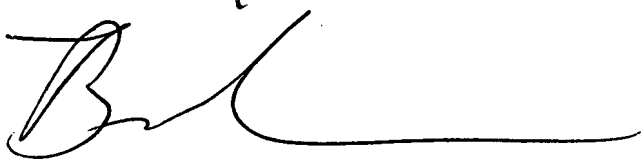
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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5 July 2007  
CER

BRIAN-YONG S. KWON  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to be 'B. Kwon', with a long horizontal line extending to the right.